Patent
Case No.: 48317US014

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	JAPUNTICH, DANIEL A.		
Application No.:	08/240877	Group Art Unit:	3761
Filed:	May 11, 1994	Examiner:	Aaron J. Lewis
Title:	FILTERING FACE MASK THAT HAS A NEW EXHALATION VALVE		

SUPPLEMENTAL APPEAL BRIEF

Board of Patent Appeals
and Interferences
Commissioner for Patents
Washington, DC 20231

CERTIFICATE OF TRANSMISSION
To Fax No.: 703-872-9303
I hereby certify that this correspondence is being facsimile transmitted to the U.S. Patent and Trademark Office on:
September 19, 2002 — Date
Signed by: Susan M. Dacko

Dear Sir:

This Supplemental Appeal Brief is being submitted pursuant to 37 CFR § 1.193(b)(2)(ii) and in accordance with the terms of Section 1208.02 of the Manual of Patent Examining Procedure. No fee should be needed for submission of this Appeal Brief since Appellants have already been charged for this appeal, but to the extent that the United States Patent and Trademark Office deems otherwise, the required fee for the appeal should be charged to Deposit Account No. 13-3723. Copies of the Exhibits can be found in the Appeal Brief mailed May 31, 2002.

REAL PARTY IN INTEREST

The real party in interest is 3M Company (formerly known as Minnesota Mining and Manufacturing Company) of St. Paul, Minnesota and its wholly owned subsidiary 3M Innovative Properties Company of St. Paul, Minnesota.

RELATED APPEALS AND INTERFERENCES

Copending U.S. Patent Application 09/678,580 had been appealed. The Appeal Brief was filed on May 6, 2002. Before filing that Brief, however, an interview was held with Primary Examiner Lewis and Supervisory Primary Examiner Weiss, and the outstanding rejection, based on a combination of UK patent application GB 2,072,516 to Simpson and French Patent 1,209,475, was withdrawn. It was Examiner Weiss's opinion that the combination was not

proper. Examiner Lewis therefore withdrew the finality of the Office Action and reopened prosecution. After filing the Appeal Brief in that case, the applicants received an Office Action (mailed May 9, 2002) that withdrew the prior art rejection based on Simpson and the French patent. Thus, the '580 application is not currently being appealed — although a brief had been filed.

STATUS OF CLAIMS

Claims 34-38, 40-74, and 78-81 are pending in this case and are the subject of this appeal.

STATUS OF AMENDMENTS

Only one amendment has been filed after the final rejection. This amendment was made to claim 66 after the Examiner reopened prosecution.

SUMMARY OF THE INVENTION

Persons who work in contaminated environments commonly wear filtering face masks over their nose and mouth to protect themselves from inhaling airborne pollutants. Many known filtering face masks have employed a cup-shaped mask body that includes a filter layer and that is adapted to fit over a wearer's nose and mouth. Exhalation valves have been used on these masks to rapidly purge exhaled air from the mask interior.

The most common exhalation valve that has been used on a filtering face mask is a "button-style" valve. These valves typically have a circular flexible flap that is mounted to a valve seat through a central stake or button. The whole circumference of the flap is generally free to be lifted from the seal surface during an exhalation. An example of a button-style valve is shown from the side in Figure 3 of UK patent application GB 2,072,516A to Simpson:

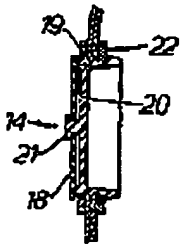


FIG. 3.

[Simpson]

Another example of a button-style valve is shown in U.S. Patent 4,873,972 to Magidson et al., assigned to Moldex/Metric Products Inc. and issued on October 17, 1989.

In addition to button-style valves, other valve structures have been used to purge exhaled air from the mask interior. For example, U.S. Patent 4,934,362 to Braun describes a valve, which when viewed from the side, has a parabolic valve seat. Like the button-style valves, the Braun valve has its flap mounted centrally to the valve seat. This central mounting, however, can interfere with the flow of exhaled air through the valve and does not allow as great a moment arm to be achieved in lifting the flap from the seal surface. Centrally-mounted valves also can cause exhaled air to be diverted into multiple flow streams.

As an alternative to these centrally-mounted valves, a "flapper-style" valve also has been disclosed as being suitable for use on filtering face masks. Figure 2 of the Simpson patent shows such a valve:

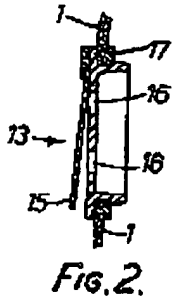


FIG. 2.

[Simpson]

This flapper-style valve includes a "flexible circular flap member 15 of, for example, plastics material, which is arranged to cover and close valve opening 16 during an inhalation and to flex away from those openings during exhalation." "To allow flexing of the flap member, a part of its peripheral portion, a segment of the flap member, is fixed in position, the remaining part of the flap member being left free." See Simpson at page 2, lines 37-50.

Although Simpson's flapper-style valve can provide a greater moment arm in lifting the flap 15 from the seal surface, it does suffer from a number of deficiencies, amongst them, the inability to keep the flap closed under any orientation of the valve. To keep its valve closed under neutral conditions — that is, when a wearer is neither inhaling nor exhaling — Simpson places the valve 12 on the top portion 1 of its duck-billed mask:

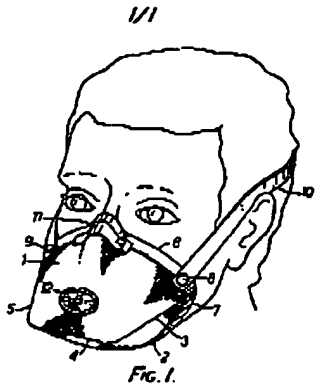


Fig. 1.

[Simpson]

Simpson does not describe how to construct a flapper-style valve where the flap is pressed against a seal surface when a wearer is neither inhaling or exhaling. Simpson's valve therefore must rely on gravity for this purpose. This reliance on gravity, however, places limits on the locations where Simpson's valve can be disposed on a cup-shaped mask without risking an influx of contaminants into the mask interior when a wearer is neither inhaling nor exhaling.

Applicants' filtering face mask includes a new exhalation valve 14 that is different in structure from and in performance over known exhalation valves:

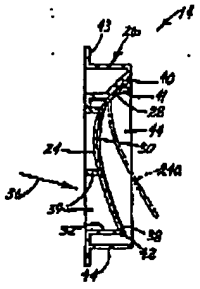


Fig. 3

[Appellants']

Applicants' exhalation valve 14 includes a single flexible flap 24 that has a stationary portion 28, one free portion 38, and a circumferential or peripheral edge that includes (i) a stationary free segment that is associated with the stationary portion 28 of the flap 24 so as to remain in substantially the same position during an exhalation and (2) a free segment that is associated with the free portion 38 of the flap so as to be movable during an exhalation. Like the Simpson valve, the free segment of the peripheral edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position. Unlike Simpson's flapper-style valve 13, however, appellants' valve 14 includes a valve seat 26 that has a flap-retaining surface 40 and a seal surface 31, which surfaces 40 and 31 are not aligned and are positioned relative to each other

to create a cross-sectional curvature of the at least one free portion of the flexible flap 24 when viewed from the side in a closed position. This nonalignment and relative positioning of these two surfaces 40 and 31 also allows the one free portion 38 of the flexible flap 24 to be pressed against the seal surface 31 when a wearer of the mask is neither inhaling nor exhaling. Although pressed against the seal surface, the flap's one free portion 38 can be lifted from the seal surface during an exhalation to allow large quantities of air to be rapidly purged from the mask interior (see appellants' specification at page 6, line 25 to page 9, line 29). This structure and its benefits are neither taught nor suggested in Simpson, which is the prior art reference that has been cited against the appellants in this appeal.

Although the different structure and benefits of applicants' invention have not been taught in the prior art, they have, however, been utilized by investigators in this field after publication of the present invention. For example, Magidson — an inventor of the subject matter used in the '972 Moldex patent mentioned above — described the use of a button-style valve on a filtering face mask in a 1988 patent application, but subsequent to the publication of appellants' invention, Magidson (in U.S. Patent 6,047,698 to Magidson et al. also assigned to Moldex-Metric Inc. and filed on August 20, 1998) describes a unidirectional flapper-style fluid valve that has a flap-retaining surface 26 that is not aligned with and is relatively positioned to a seal surface (generally referenced as a valve seat 22) to allow the flap "to be contoured to have a gentle curve inward and completely around the circumference of the valve seat 22." "The off-center contouring of the flexible flap 20 [in Magidson et al.] therefore provides for sufficient holding force for the flap 20 to lie against the seal of the valve seat 22 and to have a free end 42 and a secured end 44." See the '698 patent at column 2, lines 33-40. Thus, while investigators in the pertinent field did not appreciate the structure and function of the appellants' invention before it was published, these same investigators did choose to adopt it after it become publicly known.

ISSUES ON APPEAL

Issue - Obviousness

Appellants' independent claims 78 and 81 have been rejected based on a combination of GB 2,072,516A to Simpson and U.S. Patent 3,191,618 to McKim. While Simpson describes a flapper-style exhalation valve for a filtering face mask that operates under temperatures and

pressures generated by a human's respiratory system and at a person's breathing pace (typically 20 to 60 cycles per minute), McKim describes a curved seat reed valve for a 2-cycle engine that would operate at internal combustion temperatures and pressures and at speeds on the order of 10,000 or 12,000 revolutions per minute (rpms). McKim's reed valve is made of spring sheet material such as shim stock, and the valve has a non-aligned surface for imparting a curvature to the reed valve. Would Simpson and McKim have rendered the subject matter of claims 78 and 81 obvious to a person of ordinary skill under the terms of 35 USC § 103?

GROUPING OF CLAIMS

The appealed claims will stand or fall together with the patentability of the independent claims. No admission, however, is being made with respect to the obviousness of the subject matter of the dependent claims.

ARGUMENTS OF APPELLANTS

Issue - Obviousness Based on Simpson and McKim

Appellants' invention pertains to face mask 10 that comprises (a) a mask body 12 that is adapted to fit over the nose and mouth of a person and (b) an exhalation valve 14 that is attached to the mask body 12 directly in front of where the wearer's mouth would be when the mask is worn:

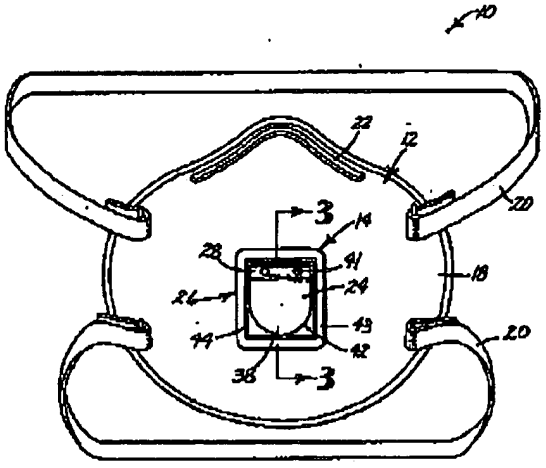


Fig. 1

[Appellants']

The exhalation valve 14 comprises (i) a valve seat 26 and (ii) a single flexible flap 24. The valve seat 26 comprises an orifice 32, a seal surface 31 that surrounds the orifice 32, and a flap retaining surface 40:

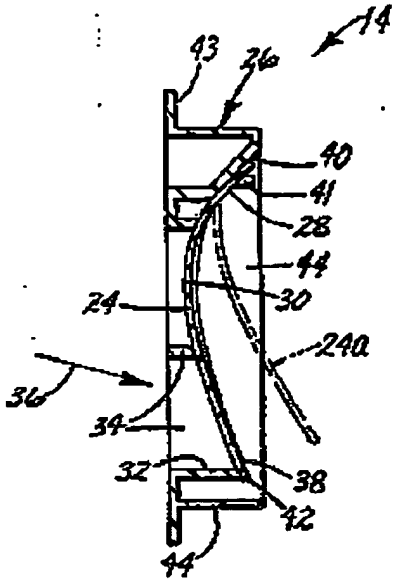


Fig. 3

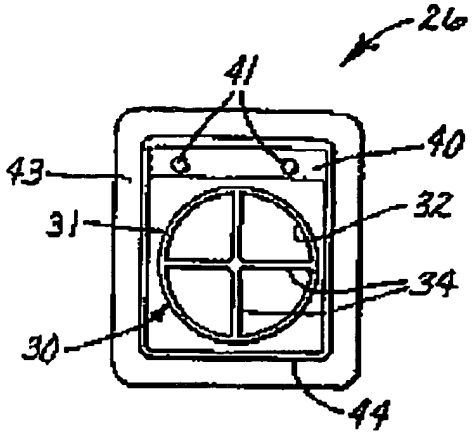


Fig. 4

[Appellants']

The single flexible flap 24 has a stationary portion 28, one free portion 38, and a circumferential or peripheral edge that includes stationary and free segments. The stationary segment of the edge is associated with the stationary portion 28 of the flexible flap so as to remain in substantially the same position during an exhalation. The free segment of the edge is associated with the one free portion 38 of the flexible flap 24 so as to be movable during an exhalation. The free segment of the peripheral edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position (see Figure 1 and Figure 4).

The flexible flap 24 is secured to the valve seat noncentrally relative to the orifice 32 (or closer to the stationary segment of the peripheral edge than to the free segment). The flap retaining surface 40 and the seal surface 31 are not aligned and are positioned relative to each other to create a cross-sectional curvature of at least the one free portion 38 of the flexible flap 24 when viewed from the side in a closed position. The nonalignment and relative positioning of the flap-retaining surface 40 and the seal surface 31 also allow the one free portion 38 of the flexible flap 34 to be pressed against the seal surface 31 when a wearer of the mask is neither inhaling nor exhaling. This

feature also allows the one free portion 38 of the flap 24 to be lifted from the seal surface 31 during an exhalation.

Simpson describes a flap valve 13 in its Figure 2 that comprises a flexible circular flap member 15:

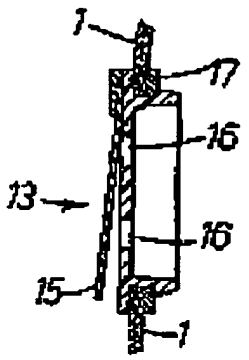
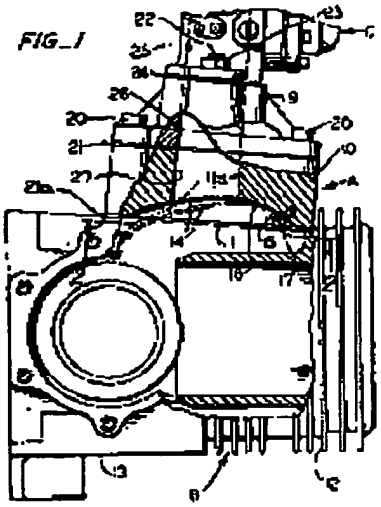


FIG. 2.

[Simpson]

The flap member 15 is made of a plastic material and is arranged to cover a closed valve opening 13 during an inhalation and to flex away from those openings during an exhalation (p. 2, lines 37-42). To allow flexing of the flap member 15, a part of its peripheral portion — that is, a segment of the flap member — is fixed in position and the remaining part of the flap member is left free (p. 2, lines 42-46). The valve is fitted in an aperture on the mask and is held in place by a retaining ring 17 (p. 2, lines 46-50). As shown in Simpson's Figure 1 reproduced above, the valve 12 is disposed on the top portion 1 of Simpson's duck-bill or pouch-shaped mask.

McKim discloses a curved seat reed valve for a 2-cycle engine:



[McKim]

The reed valve includes a valve reed 14 of spring sheet materials such as shim stock (col. 1, lines 60-61). The spring sheet material is secured by an anchor bar 15 and screws 17 to a curved seat 18 that is formed on the inner-engine side of the valve bock 10 (col. 1, lines 61-63). Curvature of the seat 18 corresponds to the normally flexed condition of the valve reed 14 when it is flexed laterally from its normally straight position as shown in Figure 3 (col. 1, lines 64-66). The normally flexed curvature of the reed is provided to eliminate float, or flutter from bounce when closing (column 1, lines 19-24; column 2, lines 55-62). The McKim valve is fashioned for use on high-speed engines, for example one that will turn at a speed on the order of 10,000 to 12,000 revolutions per minute (col. 2, lines 55-62). For a more modest speed, for example, 5,000 or 6,000 rpms, the curvature of the valve seat may be reduced to provide a freer, fuller opening of the valve at the lower speeds (column 2, lines 62-65).

This combination of documents would not have made appellant's invention obvious to a person of ordinary skill for the following reasons.

Firstly, the subject matter of applicants' invention is structurally and functionally dissimilar to the subject matter described in Simpson. Applicants' invention requires a *flap retaining surface and a seal surface that are not aligned and that are positioned* relative *to each other to allow for a cross-sectional curvature of the one free portion of the flexible flap.* Simpson shows a flap-retaining surface and seal surface that are in direct alignment with each other. Further, the Simpson flap does not possess a *curvature in cross-section* when viewed from the side elevation in the closed position. When closed, the Simpson flap would remain flat in planar alignment with its flap-

retaining surface and seal surface. In addition, the nonalignment and relative positioning of the flap-retaining surface and the seal surface in applicants' invention allow the one free portion of the flexible flap to be *pressed* against the seal surface when a wearer of the mask is neither inhaling or exhaling. An expert in the field of respirators and respirator components, David M. Castiglione, has provided evidence that establishes that the valve 13 shown in Figure 2 of the '516 U.K. Patent Application (Simpson) does not have its flap 15 *pressed* against the seal surface in an abutting relationship with it when a wearer would be neither inhaling nor exhaling. Castiglione states in paragraph 9 of his February 2, 2001 Affidavit (Exhibit A) that "there is nothing that can be discerned from Figure 2 [of Simpson] or from the [Simpson] specification that would indicate that the flap is pressed towards the seal surface in its neutral position." Another expert in the field of exhalation valves, John Bowers, (the inventor named in U.S. Patent 5,687,767) stated the following with respect to Simpson in paragraph 15 of his Declaration dated December 10, 2001 (Exhibit B):

> My review of the Simpson document reveals a flapper-style valve 13 in Fig. 2, which would not have its "flexible circular flap member 15" pressed against the valve's seal surface when a wearer of the mask is neither inhaling nor exhaling. The aligned relationship between the flap retaining surface and the seal surface and their relative positioning would not cause Simpson's flap 15 to be pressed against the valve's seal surface. At best the flap 15 would rest flush against the seal surface as a result of its securement at the flap retaining surface. The Simpson valve 13 therefore could allow for the influx of contaminants into the mask interior when, for example, a wearer tilts their head downwards and allows gravity to draw the flap away from the seal surface.

Given the aligned relationship between the flap retaining surface and the seal surface, there is no force exerted upon the flap that would bias the flap against the seal surface. The flap 15 can only reside in mere contact with the seal surface in the closed position. Simpson therefore places the exhalation valve 12 on the top portion 1 of its pouch-shaped mask (see Fig. 1 of Simpson) so that gravity can hold the valve shut when the wearer is neither inhaling nor exhaling. Gravity, however, does not constitute non-aligned seal and flap-retaining surfaces that create a cross-sectional curvature and allow for the flap to be pressed against the seal surface. As recited in claim 81, appellants' invention also requires that the *exhalation valve be attached to the mask body directly in front of where the wearer's mouth would be when the mask is worn.* Simpson does not teach or suggest such a mask because, as indicated, it must locate the exhalation valve on the top of the mask to utilize gravity to keep the valve closed.

Secondly, the secondary reference, U.S. Patent 3,191,618 to McKim, cannot be applied as a reference against applicants' invention because the McKim patent does not describe analogous art. As the Board is aware, a reference cannot be considered sufficiently analogous and thus relevant for determining obviousness unless it is either (1) within the field of the inventor's endeavor, or (2) is reasonably pertinent to the particular problem that confronted the inventor.[1] Applicants' invention resides in the field of filtering face masks that use exhalation valves. McKim does not reside within this field of endeavor: it resides in the field of gasoline engines that use reed valves.

McKim shows a curved seat reed valve that is designed for use in a 2-cycle engine, which would turn at speeds as high as 10,000 or 12,000 revolutions per minute. In contrast, applicants' invention pertains to a filtering face mask that employs an exhalation valve, which opens in response to a wearer's breathing. Castiglione explained in his November 15, 1999 Affidavit (Exhibit C) why McKim does not reside in the field of endeavor of applicants' invention:

> The field of endeavor for a filtering face mask is very different from the field of endeavor of a curved seat reed valve that is used in a high-speed engine. Persons of ordinary skill in the field of designing filtering face masks do not consult documents that describe valves for gasoline engines in developing respiratory products. Exhalation valves for respirators operate under very different conditions from valves that are used in gasoline engines and require extraordinary different design parameters.

Another investigator who works in the filtering face mask field, John L. Bowers, explains in more detail why McKim is not in the field of endeavor of a person of ordinary skill in the art designing exhalation valves:

> My review of the McKim patent shows a curved seat reed valve that is designed for use in a high-speed engine, which could turn at speeds as possibly as high as 10,000 or 12,000 revolutions per minute (rpm). The reed valve described in McKim is indicated to be particularly suited for a high speed operation where opening and closing forces are large. McKim states these forces can cause the valve to bounce (an apparent elastic recoil from impact). The stated goals in McKim are full and rapid opening, quick and complete closing, and eliminating float and bounce.
>
> The field of the above-captioned '877 invention pertains to a filtering face mask that employs an exhalation valve. A filtering face mask is worn over the nose and mouth of a person for filtering contaminants that may be present in the ambient air. Filtering face masks commonly employ exhalation valves to allow

[1] *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).

warm, moist, exhaled air to be rapidly purged from the mask interior. The exhalation valves are used to improve wearer comfort. These valves generally operate at normal room temperatures and pressures.

The field of endeavor for filtering face mask is very different from the field of endeavor of a reed valve that is used in a two-cycle engine. Exhalation valves for respirators operate under very different conditions from valves that are used in two-cycle engines and require notably different design parameters. The valve that is described in McKim has very rapid opening and closing requirements (thousands of openings and closings per minute) and operates under temperatures and pressures that differ substantially from the requirements of exhalation valves, which open and close under the much slower pace of a wearer's breathing and under temperatures and pressures that tend to vary only from the ambient to that exhibited by the wearer's exhaled air. Thus, persons of ordinary skill in the field of designing filtering face masks, to the best of my knowledge and experience, do not find valves for two-cycle engines to be in their field of endeavor and therefore do not consult documents that describe valves for these engines when developing new respiratory products.

Bowers' Affidavit, paragraphs 11-13 (Exhibit B). Another person skilled in the field of exhalation valves for filtering face masks, Frank Fabin, who has worked on one design team and led another design team in the development of a new exhalation valve, stated the following with respect to McKim:

My review of the McKim patent reveals a curved seat reed valve that is suitable for use in high rpm two-cycle engines. The reed valve comprises a thin, normally flat, single thickness, springy, sheet material, which, when relieved of external stresses will lie flat, but which is flexed lengthwise to define a curve. The reed valve is disclosed to be made of a spring sheet material, such as, for example, shim stock. The reed valve is disclosed to bear throughout its length against a valve seat, with the seating bias at the free end of the reed being as great as, or greater than, that throughout the remainder of the reed. The reed valve is indicated to be designed to seat quickly, effectively, and without float or bounce after each opening. The patent indicates that the reed valve is adaptable for use within an extremely high-speed engine, for example, one that will turn at a speed on the order of 10,000 or 12,000 revolutions per minute or at more modest speeds of 5,000 to 6,000 rpms.

In my approximately 24 years of working in occupational health, I have not — nor am I aware of another person who works in this field who has — consulted a reference in the reed valve art for gasoline engines to obtain solutions to problems encountered in developing exhalation valves that are used on filtering face masks.

Filtering face masks posses the problem of creating a warm, moist, high CO_2 content environment around the nose and mouth of a person who wears a filtering face mask. Investigators in this field have pursued a goal of purging from the mask interior the largest amount of fluid possible while using the least amount of energy.

> Investigators therefore have pursued the particular goal of designing exhalation valves that open easily in response to the exhalation pressure developed in the mask interior during an exhalation. Exhalation valves that open under minimal pressure allow the warm, moist high CO_2 content air, to be more easily removed from the mask interior and thus require the wearer to expend less energy to operate the valve over an extended period of time. Exhalation valves typically operate under ambient environmental conditions in response to exhalation pressures generated by the wearer. These conditions are remarkably different from the environment (for example, temperatures and pressures) under which a reed valve operates in a two-cycle gasoline engine. The flexible flaps that are used in exhalation valves do not deal with problems of float, or flutter from bounce in closing like the reed valves described by McKim. The opening and closing of an exhalation valve occurs in cadence with a wearer's breathing pace, which is orders of magnitude less than the high rpms under which gasoline engines operate at. For these reasons and others, persons of ordinary skill in the filtering face mask and exhalation valve art, as far as I am aware, do not examine documents that pertain to reed valves for two-cycle gasoline engines in designing filtering face masks and the exhalation valves that are used on them. Documents that describe reed valves for two-cycle gasoline engines are not in the field of endeavor of persons who design exhalation valves for filtering face masks.

Fabin Affidavit, paragraphs 8-10 (December 10, 2001) (Exhibit D). In view of this evidence, it is clear that McKim does not reside in the field of endeavor of a person who designs exhalation valves for use on filtering face masks. Because the Examiner has not put forward any evidence to the contrary, the only conclusion that can be reached is that McKim is not in applicants' field of endeavor.

Since the first element of the two-part test for evaluating whether a reference is analogous has not been satisfied, it therefore is necessary to consider whether the McKim reference is reasonably pertinent to the particular problem that concerned applicants. The Federal Circuit has explained that the USPTO needs to consider the purposes of the reference disclosure and the invention in determining whether a reference meets the second prong of the two-part test:

> A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. **Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve.** If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his intention.

If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it (emphasis added).[2]

In developing their invention, applicants sought to produce an exhalation valve that minimized exhalation pressure needed to open the valve and allowed a greater percentage of exhaled air to be purged through the exhalation valve to improve wearer comfort (see applicants' specification at page 3, line 25 to page 5, line 34 and Examples 4-6 and 8-13). The McKim reference, however, deals with solving the problem of float or bounce, which may occur when a 2-cycle engine is operating at high rpms (see McKim at column 1, lines 20-24 and column 2, lines 55-62). McKim's concern for controlling float or bounce is not reasonably pertinent to the problems that applicants were involved with — namely, providing comfort to the mask wearer by allowing the valve to open under minimal pressure and enabling a greater percentage of exhaled air to be purged through from the mask interior through the valve. As stated in the Bowers Declaration, investigators who work in the field of exhalation valves for filtering face masks are not concerned with problems of float or bounce:

> In exhalation valves for filtering face masks, the speeds for opening and closing is not a primary design parameter. There is no incumbent need to rapidly fill or exhaust a combustion chamber. Further, under the airflows and pressure drops that are encountered in a filtering face mask, "bounce or float" is not an occurring event or a problem that investigators in the exhalation valve art need to deal with. Investigators who design exhalation valves for filtering face masks seek to produce exhaust valves that remain closed between breaths and that minimize the force or pressure needed to open the valve from its normally closed position. This particular design goal is not compatible with or comparable to fast-closing valves that require high forces for rapidly opening and closing. Exhalation valves tend to open and close at the rate of a person's breathing, which is about 20 to 60 cycles per minute. In contrast, the McKim valve is designed to operate at speeds as high as 10,000 to 12,000 revolutions per minute. The flow volumes and flap stiffness are orders of magnitude higher for valves that are used in combustion engines as opposed to valves that are used on respiratory masks. For these reasons, a person of ordinary skill in the filtering face mask art would not, in my view, have found the McKim patent to be reasonably pertinent to the problems that are encountered in the development of an exhalation valve for a filtering face mask. McKim would not be a reference that would have logically commended itself to the attention of persons of ordinary skill in developing new exhalation valves for filtering face masks. I have not, nor have I witnessed, anyone who is skilled in the field of developing filtering face masks, look at the

[2] *In re Clay*, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992).

> art of valves for two-cycle engines for solutions to problems confronted by them in the exhalation valve art.

The Castiglione and Fabin declarations discussed above also explain how McKim is concerned with a problem that is of no concern to the purpose of the present invention. Because the purpose of appellants' invention is not pertinent to the problem that McKim dealt with, namely float or bounce, the second prong of the test for qualifying as an analogous reference also has not been met. A person possessing ordinary skill in the art of filtering face masks that use exhalation valves would not reasonably have been expected to solve the problem of lowering the airflow resistance force needed to open an exhalation valve through considering a reference that deals with eliminating float or bounce in a valve reed in a 2-cycle gasoline engine. As such, the obviousness rejection based on McKim cannot be properly sustained.

Thirdly, even if McKim was found to be an analogous reference, a person of ordinary skill still would not have been led to applicants' invention because the structure of the reed valve disclosed in McKim would not answer the required properties of appellants' valve. There is no evidence that the McKim reed valve would demonstrate the required flexibility of appellants' flexible flap. Appellants have defined the term "flexible" to mean that "the flap can form or bend in the form of a self-supporting arc when secured at one end as a cantilever and viewed from a side elevation (see, e.g., Fig. 5)."[3] The flap that is described in McKim is made of "spring sheet material, such as, for example, shim stock" (column 1, lines 59-61). McKim therefore is not describing a flexible flap that would be suitable for use in an exhalation valve. This fact is confirmed by Richard Betts, a person skilled in the art of two-cycle engines:

> Since 1965, the 2-cycle engines that I have either constructed or worked on have used a reed valve of varying degrees of stiffness. None of the reed valves that I have encountered, however, were "flexible" as the term has been defined in the above-captioned patent application and recited in paragraph 4 above. Reed valves that are used on 2-cycle engines can bend when exposed to a force such as shown in Fig. 3 of the McKim patent. The reed valves, however, are not so flexible that they will bend in the form of a self-supporting arc when secured at one end as a cantilever. Reed valves do not bend in the form of such an arc in response to the mere force of gravity. If the valves were constructed to have that degree of flexibility, the 2-cycle engines in which they were used would surely not be operative. If secured at one end as a cantilever and having a free end that projects

[3] Appellants' specification at page 7, lines 11-14.

> from the point of securement, a reed valve would project in an essentially straight line when viewed from a side elevation. The degree of stiffness that reed valves possess are orders of magnitude greater than the flexible flaps that are used on exhalation valves.

Declaration of Richard Betts, paragraph 5 (December 7, 2001) (Exhibit E). Because McKim's valve reed is so structurally different from the flexible flap that is used in the present invention, there would be no reason to expect — and there is no evidence in this record to indicate otherwise — that McKim's method of mounting its stiff valve reed would be suitable for a more highly flexible flap that is used on an exhalation valve. Further, the conditions under which the McKim reed valve operates (high pressure, high temperatures, 10,000 or so cycles per minute) is so remarkably different from the conditions under which an exhalation valve operates (lung pressure, exhaled air temperatures, and breathing cycles of 20-60 per minute), that there can be no expectation that any structure described in McKim would be suitable to produce an invention like the one under consideration here. Thus, the mounting requirements for the McKim cannot be transferred to an exhalation valve like Simpson's without some clear teaching or suggestion to do so...

Fourthly, the record is devoid of any teaching, suggestion, or motivation to combine the pertinent teachings of Simpson and McKim. As the Board is aware, an obviousness rejection cannot be sustained, based on a combination of references, without any evidence of why a person of ordinary skill would have been motivated to combine the pertinent teachings.[4] The suggestion to make the combination must come from the prior art.[5] It is not enough to simply identify each claimed element in the prior art.[6] "The factual inquiry whether to combine references must be thorough and searching. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with."[7]

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[4] *In re Rouffet*, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998) ("When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references.").

[5] *In re Beattie*, 24 USPQ2d 1040, 1042 (Fed. Cir. 1992) ("The question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.").

[6] *Rouffet* at 1457. ("If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability.").

[7] *In re Lee*, 61 USPQ 1431, 1433 (Fed. Cir. 2002).

Simpson's teachings are mainly concerned with producing a face mask that is in the shape of a pouch and that has an exhalation valve. Simpson's valve teachings are not concerned so much with showing how to make a low pressure drop valve that can remain closed under a variety of orientations as they are concerned with simply illustrating alternative valves that could be used on its pouch-shaped mask. And McKim's teachings are for providing a curved reed valve seat on a 2-cycle gasoline engine to reduce float or bounce. Nonetheless, the Examiner stated in the Office Action mailed September 10, 2001, that "it would have been obvious to modify the flexible flap and seat of Simpson et al. (fig. 2) to be curved because it would have provided for quick effective seating without float or bounce after each opening as taught by McKim (column 1, lines 64-72)." **The Examiner has not cited any authority for his view that eliminating float or bounce would be a problem that persons skilled in designing exhalation valves would seek to overcome.** Although not necessary to overcome the rejection, appellants have nonetheless responded to this unsupported position by furnishing testimony of an expert in the field of exhalation valves, John Bowers. Bowers stated that "under the airflows and pressure drops that are encountered in the filtering face mask, 'bounce or float' is not an occurring event or problem that investigators in the exhalation valve art need to deal with." Thus, although the motivation recited in the September 10, 2001 Office Action for combining the two references does not exist, the Examiner, in the most recent Office Action mailed February 26, 2002, has totally ignored the evidence of record in the Bowers Affidavit and continues to state that "[i]t would have been obvious to modify the flexible flap and seat of Simpson et al. (fig. 2) to be curved because it would have provided for quick effective seating without float or bounce after each opening as taught by McKim (column 1, lines 64-72)." The Examiner's refusal to cite any prior art source in support of this view is clear legal error. The Federal Circuit has explained at length in *In re Lee* that obviousness rejections based on combinations of references are improper when there is no evidence within the four corners of the record, to support the reasoning behind making the combination. Conclusory statements simply are not evidence.[8]

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[8] *See In re Lee*, 61 USPQ2d at 1434 ("With respect to Lee's application, neither the examiner nor the Board adequately supported the selection and combination of the Nortrup and Thunderchopper references to render obvious that which Lee described. The examiner's conclusory statements that "the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software" and that "another motivation" would be that the automatic demonstration mode is user friendly and it functions as a tutorial" do not adequately address the issue of motivation to combine. The factual

Not only has the Examiner erred by failing to supply the record with any evidence that supports his belief that "float or bounce" is a problem that needs to be overcome in the exhalation valve art, but the Examiner has still further erred in totally disregarding the testimony of Bowers. The reviewing courts have stated on numerous occasions that it is not proper for Examiners to disregard — or substitute their viewpoint for — the evidence supplied by persons who are skilled in the technology at hand.[9] The MPEP is in accord:

> Evidence traversing rejections must be considered by the Examiner whenever present. All entered affidavits, declarations, and other evidence traversing rejections are acknowledged and commented upon by the examiner in the next succeeding action....Where the evidence is insufficient to overcome the rejection, the examiner must specifically explain why the evidence is insufficient. General statements such as 'the declaration lacks technical validity' or 'the evidence is not commensurate with the scope of the claims' without an explanation supporting such findings are insufficient.[10]

If the Examiner chooses to continue down this path, appellants request that he furnish the record with an affidavit that shows why his view is valid over Bowers. Such an affidavit should clearly establish that persons of ordinary skill who design exhalation valves do indeed try to overcome problems of float or bounce, the Bower's declaration notwithstanding. Until there is evidence in the record, which evidence clearly shows that a person of ordinary skill would have combined the

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question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority."); *see also In re Dembiczak*, 50 USPQ 1614, 1617 (Fed. Cir. 1999) ("Broad conclusory statements regarding the teachings of multiple references, standing alone, are not 'evidence'.").

[9] *See, In re Zeidler*, 215 USPQ 490 (CCPA 1982) ("Although perception of color may, in essence, be a 'subjective' determination, we believe that an expert's evaluation in this field is entitled to more weight than that of a layman. *In re Neave*, 54 CCPA 999, 1007, 370 F.2d 961, 968, 152 USPQ 274, 279-80 (1967). Therefore, because the qualifications of Lach and the test procedures which he employed are unchallenged, the board's holding that 'a more dramatic difference in results' is required constitutes reversible error, the board having erroneously substituted its judgment for that of an established expert in the art."); *In re Fay*, 146 USPQ 47 (CCPA 1965) ("It seems to us that one as well qualified in the highly technical art of fluoride-containing halogenated compounds as Henne is shown to be is properly entitled to express his expert opinion, and that such an opinion is entitled to be given consideration with the other evidence in the case in determining whether the conclusion of obviousness is supported by the opinion of the examiner as to what the prior art teaches. For the reasons previously stated we do not think the prior art teachings furnish factual support for the examiner's opinion."); *see also In re Alton*, 37 USPQ2d 1578 (Fed. Cir. 1996) ("We do, however, hold that the examiner's final rejection and Answer contained two errors; (1) viewing the Wall declaration as opinion evidence addressing a question of law rather than a question of fact; and (2) the summary dismissal of the declaration, without an adequate explanation of why the declaration failed to rebut the Board's *prima facie* case of inadequate description.").

[10] MANUAL OF PATENT EXAMINING Procedure § 2144.03, 2100-129 (August 2001).

teachings of Simpson with McKim, the obviousness rejection based on these references cannot be properly held to constitute a *prima facie* case of obviousness.[11]

Fifthly, the Simpson and McKim documents each present very good evidence of a lack of motivation to combine their respective teachings. The McKim technology was known to persons of ordinary skill before the Simpson publication. Nonetheless, Simpson did not employ the McKim technology in its flapper-style exhalation valve, even though Simpson and McKim both disclose flapper-style valves (albeit in entirely different fields). If the use of a curved flexible flap, and the particular structure necessary for creating that curvature and causing the flap to be pressed towards the seal surface, would have been obvious to a person of ordinary skill in making a flapper-style exhalation valve, you would have expected a person skilled in the exhalation valve art to have used that technology in a valve like Simpson's. The Board should notice that a very long time has passed since McKim's publication in 1962 and its disclosure of a curved flapper-style valve, but that particular technology did not find its way into use in the exhalation valve art at any point over this large time span. If this aspect of the present invention would have been obvious to a person of ordinary skill, the skilled artisan in the respirator art would have been expected to employ it sometime within those years. A prolonged existence of unused technology provides very good evidence of nonobviousness.[12] Simpson, which was published almost 20 years after McKim and filed more than about 12 years before the effective filing date of the present application, also did not use this technology or find it to have been obvious. Nor did any other investigator in the filtering face mask art, either prior to or after Simpson (but before applicants' invention). Thus, the prior knowledge of the McKim technology and the long time that has elapsed since McKim's first publication, coupled with the failure to use this technology in a flapper valve system, presents very

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[11] *See Lee* at 1458. (The Federal Circuit reversed a decision of the Board because it "did not, however, explain what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination.").

[12] *See Al-Site Corp. v. Opti-Ray Inc.*, 28 USPQ2d 1915, 1922 (E.D.N.Y. 1993) ("Second, the prior art existed for many years and yet those skilled in the art never created a hanger mechanism comparable to Al-Site's patented invention. See *id.* at 1577."); see also, *Panduit Corp. v. Dennison Mfg. Co.*, 1 USPQ2d 1593, 1604-05 (Fed. Cir. 1987) ("We cannot see why the district court's first set of findings did not require a conclusion that Caveney's inventions, which had for years escaped others who sought them, "would not have been obvious" under § 103; nor why Panduit and Dennison wasted research resources for years if Caveney's inventions were obvious to all throughout those years; nor how the prior art made Caveney's eminently successful inventions obvious to the court in 1984 when it had not made them obvious to skilled engineers (each more skilled than the 'ordinary mechanic' referred to in *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 261, 13 L.Ed. 683 (1851)) who had been designing unsuccessful or far less successful cable ties for years when Caveney's inventions were made in the 1960's.").

good evidence that applicants' invention would not have been obvious to a person of ordinary skill within the meaning of 35 U.S.C. § 103.[13]

Sixthly, the prior art also fails to teach or suggest the advantages that applicants' invention can provide. An invention's advantages must be considered under the "invention as whole" concept set forth in 35 USC § 103.[14] Advantages that are not appreciated by the prior art also provide very good evidence of nonobviousness.[15] In the present case, applicants' invention possesses the benefit of achieving a low pressure drop value during an exhalation while also preventing the influx of contaminants through the valve under any orientation. Simpson's valve, however, only protects to the wearer at the most critical time — during an inhalation. When a wearer of the Simpson mask inhales, the flap becomes firmly pressed against the seal surface. But when the wearer is neither inhaling nor exhaling, and has their head tilted downward, gravity can cause the flap to droop away from the seal surface. Simpson's valve may allow contaminants to enter the mask interior in this instance. To counter this problem, Simpson mounts its valve on the top of the mask body so that gravity can be used to keep the flap closed under neutral conditions. If the valve was mounted to the underside of the mask, the flap would dangle away from the seal surface. The Simpson valve, unlike applicants' invention, therefore, has limited suitable mounting positions on its mask body. And, even if it was mounted to the top of the mask body, it could still allow contaminants to enter the mask interior when the user fully tilts their head downward.

Applicants teach persons of ordinary skill how to make a low pressure drop flapper-style exhalation valve that will preclude contaminant influx under all orientations of the mask. This is achieved by the relationship between the seal surface and the flap-retaining surface and the curved configuration that is imparted to the flap and its being pressed against the seal surface under neutral conditions. Applicants' valve also does not have to be disposed on the top side of the mask. Applicants' invention, therefore, enables the valve to be disposed on the mask directly in the path of the exhale flow stream — that is, centered on the front of the mask (see Fig. 1) — so that the valve can use the full momentum of the exhaled air stream to lift the flap from the seal surface.

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[13] *See In re Ehringer*, 146 USPQ 31, 37, CCPA (1965) ("Thus over 40 years elapsed in this art prior to appellant's filing date without anyone suggesting so far as the art cited shows, a non-sag *thoriated* tungsten filament or any way of producing it.").

[14] *In re Papesch*, 137 USPQ 43 (CCPA 1963).

[15] *See, e.g., In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1989) (Advantages not appreciated by prior art.).

As indicated in paragraphs 15 and 16 of the Bowers Declaration (Exhibit B), the Simpson flap would droop open when the wearer tilts their head downward:

> My review of the Simpson document reveals a flapper-style valve 13 in Fig. 2, which would not have its "flexible circular flap member 15" pressed against the valve's seal surface when a wearer of the mask is neither inhaling nor exhaling. The aligned relationship between the flap retaining surface and the seal surface and their relative positioning would not cause Simpson's flap 15 to be pressed against the valve's seal surface. At best the flap 15 would rest flush against the seal surface as a result of its securement at the flap retaining surface. The Simpson valve 13 therefore could allow for the influx of contaminants into the mask interior when, for example, a wearer tilts their head downwards and allows gravity to draw the flap away from the seal surface.
>
> The Simpson product also has the valve located on the upper portion 1 of the pouch-shaped mask. This has the disadvantage that the warm moist exhaled air may be directed towards the eyes, causing misting of the eyewear. And Simpson's Fig. 2 valve cannot be positioned on the underside of the mask because the flap 15 would droop away from contact with the valve seat, causing the valve to leak.

The failure of Simpson to appreciate the benefits of applicants' invention and instead teach a more deficient construction further establishes the nonobviousness of applicants' invention. McKim, of course, does not address these benefits to the slightest degree because it is a reference that resides in an entirely different field and deals with entirely different problems under entirely different conditions. In brief, the prior art does not teach or suggest the construction of applicants' valve, and it does not appreciate the benefits that that construction invention can provide. Under such circumstances, Simpson and McKim would have rendered applicants' invention obvious to a person of ordinary skill within the meaning of 35 USC § 103.

Seventhly, the copying of the technology of the present invention shortly after its publication further establishes the non-obviousness of the present invention. In a number of cases, the reviewing courts have relied on evidence of copying to find an invention to be not obvious to a person of ordinary skill.[16] For example, in *Specialty Composites v. Cabot Corporation,*[17] the

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[16] *See e.g., All-Site Corp.*, 28 USPQ2d at 1923 ("This Court also finds that the patented hanger card was not obvious in light of the prior art because Opti-Ray's design staff copied the version depicted in Al-Site's earlier '532 patent. At trial, Jimmy Vianu, Vice President of Manufacturing for Opti-Ray, was called as an adverse witness by Al-Site. Vianu conceded that he possessed copies of Al-Site's patented hanger card while designating Opti-Ray's version."); *Avia Group International, Inc. v. L.A. Gear California, Inc.*, 853 F.2d 1557, 1564, 7 USPQ2d 1548, 1554 (Fed. Cir. 1988) (Copying is additional evidence of nonobviousness."); *Diversitech Corp. v. Century Steps, Inc.* 850 F.2d 675, 679, 7 USPQ2d 1315, 1319 (Fed. Cir. 1988) ("Copying is an indicium of nonobviousness, and is to be given proper

Federal Circuit stated that "[c]opying the claimed invention, rather than one in the public domain, is indicative of unobviousness."[18] As the Board is aware, secondary considerations like copying must always be considered in connection with an obviousness determination.[19]

Attached to this Appeal Brief is an Affidavit of Brian S. McGinley (Exhibit F), the Product Marketing Manager for the Occupational Health & Environmental Safety Products Division at 3M. Mr. McGinley has worked in the respiratory field for the past 18 years and is very familiar with the art pertaining to personal respiratory protection devices. He is also familiar with the subject matter of this patent application and has witnessed the evolution of the art in respiratory products, in particular the evolution of the exhalation valve art in filtering face masks. A reading of his Affidavit and an examination of the competitive products reveals that a number of companies have appropriated the technology that is claimed in the present application. As McGinley indicates, the developments by these companies all occurred subsequent to 3M's introduction and publication of the exhalation valve that is employed in the filtering face mask of applicants' invention. 3M first published the technology of the present invention in 1993. Shortly thereafter, Racal Health & Safety used technology of the present application. Indeed, John Bowers, the inventor in the Racal patent U.S. 5,687,767 states that he used the 3M valve and applicants' published application as a starting point in the development of his valve:

> While working at Racal, I was assigned the responsibility to develop a new exhalation valve for its respiratory masks. Racal had a number of customer requests for a mask that had an exhalation valve to purge warm, moist air from the mask interior. In considering candidates for exhalation valves on our respiratory products, I initially looked at conventional button-style valves. These valves, however, were not selected for widespread commercialization of Racal face masks because the cracking pressure required to open the button-style valve was found to be relatively high. I found that the central pivoting point created an undesirably higher opening force.

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weight."); *Windsurfing International, Inc. v. AMF Inc.*, 782 F.2d 995, 1000, 228 USPQ 562, 565 (Fed. Cir. 1986), ("copying the claimed invention, rather than one within the public domain, is indicative of non-obviousness").

[17] 6 USPQ2d 1601, (Fed. Cir. 1988).

[18] *Id.* at 1608.

[19] *See In re Sernaker*, 217 USPQ 1, 7 (Fed. Cir. 1983) ("If, however, a patent applicant properly presents evidence relating to these secondary considerations, the board must always consider such evidence in connection with the determination of obviousness."); see also *W.L. Gore & Assoc. Inc. v. Garlock, Inc.*, 220 USPQ 303, 313 (Fed. Cir. 1983) ("As discussed more fully below, the district court erred in specifically declining to consider the objective evidence of nonobviousness."); Manual of Patent Examining Procedure 2100-90 (Feb. 2000).

> As part of the process for designing a new valve, I examined the exhalation valve that was recently commercialized by 3M. This valve is described in U.S. Patent 5,325,892 to Japuntich et al. I not only examined an actual commercial embodiment of the 3M valve, but I also carefully reviewed the disclosure of the '892 3M patent.

Bowers states that the technology of having a flapper-style valve where the free portion of the flap is pressed against the seal surface in a curved fashion were discovered in his examination of the 3M valve:

> My evaluation of the 3M valve showed a product that had better performance than the conventional button-style valves. This evaluation led me in pursuit of developing a flapper-style valve similar to the 3M valve. The valve that was ultimately designed by me for Racal was the flapper-style unidirectional fluid valve that is shown in U.S. Patent 5,687,767 to Bowers, and a sample of which is attached to this Declaration as Exhibit G. I sought to design a valve that would avoid infringement of the issued 3M '892 patent and would be patentable over its disclosure. The filtering face mask that was developed, which employed the new Racal valve that I developed, did possess some features similar to the 3M valve and borrowed technology learned from the 3M valve. In particular, I designed the exhalation valve for Racal so that the flexible flap of the Racal valve was secured non-centrally relative to the orifice and had a free portion that was pressed against the seal surface when a wearer was neither inhaling nor exhaling, and the flap had a curvature in the free portion when viewed from the side elevation in a closed position (although the Racal valve that I designed was also made to have a transverse curvature). The flap was also designed to have stationary and free portions with a circumferential or peripheral edge that had stationary and free segments, respectively. The flap was secured to the valve seat at the flap-retaining surface closer to the stationary segment of the peripheral edge than to the free segment. Other than the transverse curvature, the features described in the three previous sentences were present in the 3M valve and were discovered from my examination of the 3M product and the published '892 patent. The Racal valve thus was able to remain closed under neutral conditions under any orientation, like the 3M valve, to prevent the influx of contaminants and was also able to open under a relatively small exhalation force.

Following Racal, Moldex Metric introduced a similar exhalation valve product in 1998:

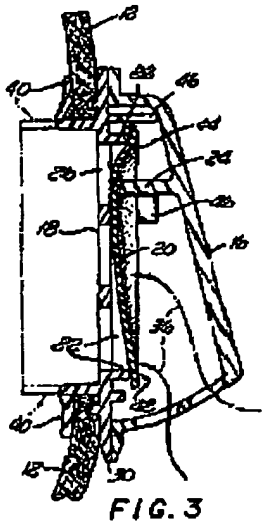

FIG. 3

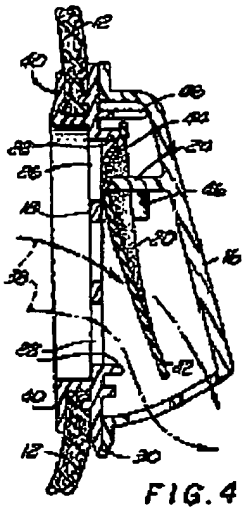

FIG. 4 [Magidson et al.]

and this was followed by the introduction of yet another product by a Korean company, Evergreen Co. Ltd., in 1999. In 2000, both the Louis M. Gerson Company and Survivair (owned by Bacou) also introduced filtering face masks that had all the limitations of the subject matter of the present invention. If you examine the Moldex, Evergreen, Gerson, and Survivair products, you will see that each has its non-centrally located flap-retaining surface that is non-aligned and positioned relative to each other to allow for a cross-sectional curvature of the free portion of the flexible flap when viewed from the side. In fact, U.S. Patent 6,047,698 to Magidson et al. was filed on August 20, 1998, after appellants' invention was publicly disclosed. If you look at Moldex' work prior to the effective filing date of the present case, you will see that Magidson's filtering face mask work included button-style valves (see U.S. Patent 4,873,972). But the more recent '698 Magidson patent states the benefits of using the technology claimed in this patent application:

> The off center contouring of the flexible flap 20 therefore provides for a sufficient holding force for the flap 20 to lie against and seal to the valve seat 22 and to have a free end 42 and a secured end 44.

(Column 2, lines 27-40). The use of the technology of appellants' invention, by a number of other respiratory product manufacturers, provides very good evidence that the subject matter of the present invention would not have been obvious to a person of ordinary skill. Although Simpson's and McKim's teachings had been known for many years before applicants' filing date, none of the entities referred to in the McGinley Affidavit had previously introduced a product that is similar to the exhalation valve that is described and claimed in the present application. The introduction of

these products shortly after the publication of 3M's technology, however, further establishes that person's skilled in the filtering face mask field surely did not find obvious the subject matter of the present invention.

In short, appellants' invention would not have been obvious to a person of ordinary skill because the primary reference to Simpson fails to teach or suggest a number of the basic elements of applicants' invention. Simpson does not have the flap-retaining surface non-aligned and positioned relative to the seal surface to create a curvature in the flap. Simpson's flap is not curved, and it is not pressed against the seal surface. Simpson therefore places its exhalation valve on the top portion of its pouch-shaped mask so that gravity can keep the flap closed under neutral conditions. In this position, however, Simpson's valve can fog the wearer's eyeglasses, and it cannot take the best advantage of the momentum of the exhaled airflow to open the valve. Simpson thus also fails to suggest placing the valve on the mask directly in front of where the wearer's mouth would be when the mask is worn. Further, the secondary reference to McKim is not applicable prior art because it is not analogous. In addition, McKim does not describe a flexible flap, and the record clearly shows that a person of ordinary skill in the exhalation valve art would not have been concerned with McKim's goals of controlling float and bounce of a reed valve. Moreover, the record is devoid of any teaching, suggestion, or motivation to combine the teachings of Simpson and McKim. Indeed, Simpson and McKim present very good evidence for a lack of motivation to combine their teachings because McKim's technology was never mentioned in Simpson or any other exhalation valve document despite it being known for many years. The prior art documents also do not teach or suggest the benefits that applicants' invention may provide. And finally, the copying of the technology claimed in the present application by competitors further establishes that applicants' invention would not have been obvious to a person of ordinary skill within the meaning of 35 U.S.C. § 103.

CONCLUSION

For the foregoing reasons, appellants respectfully submit that the Examiner has erred in rejecting this application under 35 USC § 103. Please reverse the decision below.

Respectfully submitted,

September 19, 2002
Date

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APPENDIX

78. A filtering face mask that comprises:

(a) a mask body that is adapted to fit over the nose and mouth of a person and that has a filtering layer for filtering air that passes through the mask body; and

(b) an exhalation valve that is attached to the mask body, which exhalation valve comprises:

(i) a valve seat that comprises an orifice, a seal surface surrounding the orifice, and a flap retaining surface; and

(ii) a single flexible flap that has a stationary portion and one free portion and a circumferential edge that includes stationary and free segments, the stationary segment of the circumferential edge being associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation, and the free segment of the circumferential edge being associated with the one free portion of the flexible flap so as to be movable during an exhalation, the free segment of the circumferential edge being disposed beneath the stationary segment when the valve is viewed from the front in an upright position;

the flexible flap being secured to the valve seat non-centrally relative to the orifice at the flap retaining surface, which flap retaining surface and seal surface are nonaligned and positioned relative to each other to allow for a cross-sectional curvature of at least the one free portion of the flexible flap when viewed from the side in a closed position, the nonalignment and relative positioning of the flap-retaining surface and the seal surface also allowing for the one free portion of the flexible flap to be pressed against the seal surface when a wearer of the mask is neither inhaling nor exhaling and to allow for the one free portion of the flexible flap to be lifted from the seal surface during an exhalation.

34. The filtering face mask of claim 78, wherein the flexible flap has an inflection free curvature when viewed in cross-section from a side elevation in the closed position.

35. The filtering face mask of claim 78, wherein the seal surface of the valve seat has a curvature when viewed from a side elevation.

36. The filtering face mask of claim 78, wherein the flexible flap is mounted to the valve seat in cantilever fashion.

37. The filtering face mask of claim 78, wherein the exhalation valve also includes a valve cover, the flexible flap being held in position between the valve seat and the valve cover by mechanical clamping.

38. The filtering face mask of claim 78, wherein the outline shape of the orifice does not wholly correspond to the outline shape of the seal surface.

40. The filtering face mask of claim 78, wherein the valve seat comprises cross members that are disposed within the orifice to define four openings through which exhaled air can pass during an exhalation to lift the free portion of the flap from the seal surface.

41. The filtering face mask of claim 78, wherein the valve seat includes cross members that are disposed within the orifice and are recessed beneath the seal surface.

42. The filtering face mask of claim 40, wherein the valve seat includes cross members that are recessed beneath the seal surface.

43. The filtering face mask of claim 78, wherein the mask body includes an opening through which exhaled air passes before passing through the orifice of the valve seat, the opening in the mask body having a cross-sectional area that is at least the size of the orifice.

44. The filtering face mask of claim 78, wherein the flexible flap is pressed towards the seal surface such that there is a substantially uniform seal when the valve is in a closed position.

45. The filtering face mask of claim 78, wherein the flap-retaining surface is spaced from the orifice at about 1 to 3.5 millimeters.

46. The filtering face mask of claim 78, wherein the flap-retaining surface is spaced from the orifice at about 1 to 2.5 millimeters.

47. The filtering face mask of claim 78, wherein the valve seat is made from a relatively light-weight plastic that is molded into an integral one-piece body.

48. The filtering face mask of claim 47, wherein the valve seat has been made by an injection molding technique.

49. The filtering face mask of claim 78, wherein the seal surface is substantially uniformly smooth to insure that a good seal occurs between the single flexible flap and the seal surface.

50. The filtering face mask of claim 78, wherein the flexible flap is made from a material that is capable of allowing the flap to display a bias towards the seal surface.

51. The filtering face mask of claim 78, wherein the flexible flap would normally assume a flat configuration when no forces are applied to it.

52. The filtering face mask of claim 78, wherein the flexible flap is elastomeric and is resistant to permanent set and creep.

53. The filtering face mask of claim 78, wherein the flexible flap is made from an elastomeric rubber.

54. The filtering face mask of claim 78, wherein the flexible flap has a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hours at 70 °C.

55. The filtering face mask of claim 78, wherein the flexible flap provides a leak-free seal according to the standards set forth in 30 CFR § 11.183-2, July 1, 1991.

56. The filtering face mask of claim 78, wherein the flexible flap is made from a crosslinked polyisoprene.

57. The filtering face mask of claim 78, wherein the flexible flap has a Shore A hardness of about 30 to 50.

58. The filtering face mask of claim 78, wherein the flexible flap has a generally uniform thickness of about 0.2 to 0.8 millimeters.

59. The filtering face mask of claim 78, wherein the flexible flap has a generally uniform thickness of about 0.3 to 0.6 millimeters.

60. The filtering face mask of claim 78, wherein the flexible flap has a generally uniform thickness of about 0.35 to 0.45 millimeters.

61. The filtering face mask of claim 78, wherein the circumference of the one free portion of the flexible flap has a profile that comprises a curve and is cut to correspond to the general outline shape of the seal surface.

62. The filtering face mask of claim 78, wherein the flexible flap is greater than one centimeter wide.

63. The filtering face mask of claim 78, wherein the flexible flap is 1.2 to 3 centimeters wide and is about 1 to 4 centimeters long.

64. The filtering face mask of claim 78, wherein the stationary segment of the circumferential edge of the flexible flap is about 10 to 25 percent of the total circumferential edge of the flexible flap, with the remaining 75 to 90 percent being free to be lifted from the seal surface.

65. The filtering face mask of claim 78, wherein the valve seat includes a flange that provides a surface onto which the exhalation valve can be secured to the mask body.

66. The filtering face mask of claim 64, wherein a flange extends 360 degrees around the valve seat where the valve seat is mounted to the mask body.

67. The filtering face mask of claim 78, wherein the flexible flap is positioned on the valve such that exhaled air is deflected downward during an exhalation when the filtering face mask is worn on a person.

68. The filtering face mask of claim 78, wherein the mask body is cup-shaped and includes an outer shaping layer.

69. The filtering face mask of claim 78, wherein the mask body is cup-shaped and comprises (1) a shaping layer for providing structure to the mask, and (2) a filtration layer.

70. The filtering face mask of claim 69, wherein the shaping layer is located outside of the filtration layer on the mask body.

71. The filtering face mask of claim 78, wherein a high percentage of the exhaled air is purged through the exhalation valve.

72. The filtering face mask of claim 78, wherein at least 60 percent of the total airflow flows through the exhalation valve under a normal exhalation test.

73. The filtering face mask of claim 78, wherein at least 73 percent of the total airflow flows through the exhalation valve under a normal exhalation test.

74. The filtering face mask of claim 78, wherein the exhalation valve is positioned on the mask body substantially opposite to a wearer's mouth when the mask is being worn.

79. The filtering face mask of claim 78, wherein greater than 50% of the airflow that enters the filtering face mask exits the filtering face mask through the exhalation valve when the airflow exceeds 30 liters per minute under a normal exhalation test.

80. The filtering face mask of claim 78, wherein the seal surface resides on a seal ridge of the valve seat.

81. A filtering face mask that comprises:

(a) a cup shaped mask body that is adapted to fit over the nose and mouth of a person; and

(b) an exhalation valve that is attached to the mask body directly in front of where the wearer's mouth would be when the mask is worn, which exhalation valve comprises:

(i) a valve seat that comprises an orifice, a seal surface surrounding the orifice, and a flap retaining surface; and

(ii) a single flexible flap that has a stationary portion, one free portion, and a peripheral edge that includes stationary and free segments, the stationary segment of the peripheral edge being associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation, and the free segment of the peripheral edge being associated with the one free portion of the flexible flap so as to be movable during an exhalation, the free segment of the peripheral edge being disposed beneath the stationary segment when the valve is viewed from the front in an upright position;

the flexible flap being secured to the valve seat at the flap retaining surface closer to the stationary segment of the peripheral edge than to the free segment, the flap retaining surface and seal surface are nonaligned and positioned relative to each other to create a cross-sectional curvature of at least the one free portion of the flexible flap when viewed from the side in a closed position, the securement of the flexible flap at the flap-retaining surface allowing for the one free portion of the flexible flap to be pressed against the seal surface when a wearer of the mask is neither inhaling nor exhaling and allowing for the one free portion of the flexible flap to be lifted from the seal surface during an exhalation.